UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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MICHAEL E. CRIDEN, Individually And on Behalf of All Similarly Situated,	:	CIVIL ACTION No.
Plaintiff,	:	MAGISTRATE JUDGE Alexander
	:	CLASS ACTION COMPLAINT FOR VIOLATION OF FEDERAL SECURITIES LAWS
vs.	:	
BIOPURE CORPORATION, THOMAS A. MOORE and CARL W. RAUSCH	:	JURY TRIAL DEMANDED
Defendants.	:	

Plaintiff, Michael E. Criden, individually and on behalf of all others similarly situated, by and through his attorneys, allege the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge.

NATURE OF THE ACTION

1. Plaintiff Michael E. Criden brings this action as a class action on behalf of a class (the "Class") consisting of themselves and all other persons or entities that purchased the common stock of Biopure Corporation ("Biopure" or the "Company") during the period March 5, 2003 through December 24, 2003, inclusive (the "Class Period"). Plaintiff seeks to recover damages caused to the Class by defendants' violations of the federal securities laws.

2. Biopure is a biotechnology company that develops, manufactures and markets oxygen therapeutics, a new class of pharmaceuticals that are intravenously administered to

deliver oxygen to the body's tissues. The Company's main product is Hemopure [hemoglobin glutamer 250 (bovine)], or HBOC-201, an investigational product for the treatment of acutely anemic surgical patients and for the elimination, delay or reduction of red blood cell transfusions in these patients. Hemopure is a human blood substitute derived from cow's blood, which acts like red blood cells to deliver oxygen to the body. Unlike donated blood, Hemopure does not have to be matched to a patient's blood type. In July 2002, Biopure submitted a biologic license application ("BLA") to the U.S. Food and Drug Administration ("FDA") seeking regulatory approval to market Hemopure in the U.S. for use in orthopedic surgery. In March 2003, Biopure filed a separate application with the FDA for permission to begin new clinical trial testing of Hemopure with hospitalized trauma patients.

3. Throughout the Class Period, defendants engaged in a scheme to inflate artificially the market price of Biopure securities and to defraud class members by making misrepresentations and nondisclosures of material fact concerning Biopure's prospects for FDA approval of the marketing of Hemopure for use in orthopedic patients and in trauma situations.

4. Defendants knew by virtue of their ongoing communications with the FDA that the FDA had strong reservations about Hemopure's safety, particularly as to its use with trauma patients. In fact, the FDA found that adverse data from the Company's Phase III orthopedic surgery trials (which were submitted in connection with both the orthopedic and trauma applications) raised serious safety concerns, including the death of patients. The FDA was so concerned that it placed Biopure's trauma study application on "clinical hold" and requested a host of additional information from Biopure that will severely delay any possible approval of Hemopure for use in orthopedic surgery until, at best, that latter-half of 2004.

5. Notwithstanding these material concerns raised by the FDA, defendants continually represented throughout the Class Period that they were optimistic of achieving FDA approval to market Hemopure to orthopedic patients. Moreover, while the Company repeatedly expressed its desire to expand Hemopure's use to trauma situations, the Company never disclosed to the public that it had actually filed its trauma study application with the FDA and that the FDA had repeated blocked the trauma trials, citing safety concerns.

6. Then, on Wednesday, December 24, 2003, after the close of the markets on Christmas Eve, defendants announced a potential SEC inquiry for securities fraud and, for the first time, disclosed material problems with its Hemopure product and the FDA approval process. First, the Company announced that on Monday, December 22, 2003, the Company received a "Wells Notice" from the U.S. Securities and Exchange Commission ("SEC"). The SEC sends a Wells notice to a company or an individual after its staff has completed an investigation and determined that sufficient wrongdoing has occurred to warrant civil charges to be filed. Here, the SEC sent a Wells notice to Biopure, defendant Moore and Howard Richman, Biopure's former vice president of regulatory affairs, for failing to adequately disclose material information about Biopure's communications with the FDA concerning the Hemopure applications. Second, the Company revealed – for the first time – that in March 2003, it sought FDA permission to begin new clinical trial testing of Hemopure in hospitalized trauma patients and that the FDA had repeatedly denied the request. According to the December 24th Press Release, the FDA refused to allow the study because of material "safety concerns" stemming from the company's Phase III orthopedic surgery trial. The FDA placed a "clinical hold" on any trauma trials, and requested more information, including additional animal studies, before Hemopure could be tested in

humans under trauma conditions. Despite Biopure's supplemental filings, on July 30, 2003, the FDA again denied Biopure's request that it lift its "clinical hold", barring any Hemopure trauma trials. It was not until almost five months later that Biopure shareholders learned of the trauma application, its material deficiencies and its rejection by the FDA.

7. In response to this announcement, the market price of Biopure common stock plummeted 14 percent from a closing price of $2.82 per share on December 24, 2003 to a closing price of $2.43 per share on December 26, 2003. Biopure's stock continued its decline on Monday, December 29, 2003, closing at $2.43 per share, far from the Class Period high of $8.25 per share.

8. Before disclosing the negative FDA communications and before the collapse of Biopure's stock price, the defendants substantially profited from their inflation of Biopure's stock price. In July 2003, Biopure sold over $17 million in common stock in a private placement offering. Moreover, defendant Rausch reaped almost $1.6 million in illicit insider trading proceeds during the Class Period.

JURISDICTION AND VENUE

9. This action arises under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. 240.10b-5.

10. This Court has jurisdiction of this action under Section 27 of the Exchange Act and 15 U.S.C. § 78aa, 28 U.S.C. § 1331.

11. Venue is proper in this District pursuant to Section 27 of the Exchange Act, and 28 U.S.C. § 1391(b). Many of the acts alleged herein, including the dissemination to the

investing public of false and misleading statements, occurred in substantial part in this District. In addition, defendants' principal place of business and executive offices are located in this District.

12. In connection with the acts and conduct complained of, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including the mails, interstate telephone communications, and the facilities of a national securities exchange.

THE PARTIES

13. Plaintiff, Michael E. Criden purchased shares of Biopure on the open market during the Class Period, as set forth in the annexed certifications, and suffered damages thereby.

14. Defendant Biopure is a corporation organized and existing under the laws of Delaware. Biopure maintains its principal executive offices at 11 Hurley Street, Cambridge, MA 02141.

15. Defendant Thomas A. Moore is the President and Chief Executive Officer of Biopure.

16. Defendant Carl W. Rausch was a co-founder and former chief executive of Biopure. Rausch currently serves as Biopure's Chief Technical Officer. During the Class Period, Rausch sold over 246,000 shares of Biopure for gross proceeds over $1.59 million.

17. Collectively, defendants Moore and Rausch are referred to as the "Individual Defendants".

18. During the Class Period, the Individual Defendants, as senior officers of Biopure, were privy to confidential and proprietary information concerning Biopure, its operations, and present and future business prospects. The Individual Defendants had access to material adverse

non-public information about Biopure's business, including the prospects for U.S. approval of Hemopure for use with orthopedic patients and in trauma situations. The Individual Defendants knew or recklessly disregarded that the adverse facts specified herein were misrepresented and concealed from the investing public.

19. The Individual Defendants are liable as direct participants in the violations of law complained of herein. In addition, Moore and Rausch were "controlling persons" within the meaning of Section 20 of the Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein.

20. As senior executive officers and as controlling persons of a publicly-traded company whose securities were and are registered with the SEC pursuant to the Exchange Act, and were traded over the NASDAQ National Market System, and governed by the federal securities laws, the Individual Defendants had a duty to speak the truth with respect to the prospects for FDA approval of Hemopure for use with orthopedic patients and in trauma situations, and to correct any previously issued statements that had become materially misleading, so that the market price of Biopure's securities would be based upon truthful and accurate information. Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

FALSE AND MISLEADING STATEMENTS

21. On March 5, 2003, defendants filed a Form S-3 with the SEC, registering to sell up to 10 million shares of Biopure common stock to the public (the "Form S-3"). In the Form S-3, defendants disclosed the current status of the Hemopure application with the FDA, noting: "We believe that our completed pivotal Phase III clinical trials are consistent with the FDA's

most recent guidance on the design and efficacy and safety endpoints required for approval of products such as Hemopure for use in surgical indications." The Company also noted its plans to expand applications for Hemopure through filing additional FDA applications, stating:

> The FDA requires a separate approval for each proposed indication for the use of Hemopure in the United States. We have applied for an indication for Hemopure that will only involve its perioperative use in patients undergoing orthopedic surgery. Subsequently, we expect to expand Hemopure's indications. To do so, we will have to design additional clinical trials, submit the trial designs to the FDA for review and complete those trials successfully.

22. In response to the filing, the price of Biopure shares rose 9 cents to $3.59. As *Bloomberg News* reported, "At the latest price, selling all 10 million shares would raise $35.9 million, before expenses."

23. On the same day, defendants issued a press release announcing that Biopure had signed a Cooperative Research and Development Agreement ("CRADA") with the U.S. Naval Medical Research Center ("NMRC") "that will enable the NMRC to participate in a pivotal clinical trial of the company's investigational oxygen therapeutic Hemopure(R) . . . in pre-hospital trauma." (the "March 5th Press Release"). The Company announced that the trauma trial "is intended to lead to [FDA] approval of Hemopure for pre-hospital military and civilian trauma applications . . ." The March 5, 2003 Press Release also acknowledged that the FDA was "currently reviewing Biopure's biologic license application (BLA) to market the product in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery." The Company also noted that it "is currently preparing to submit a Phase II study protocol to the FDA for a randomized, standard-therapy controlled trauma trial of Hemopure in hospital emergency rooms."

24. In the March 5th Press Release, defendant Moore commented on the Company's Hemopure product and the trauma trials, stating: "Our product introduction plan is to build awareness and understanding of this first-in-class product in surgical use and then expand into trauma following the successful completion of our DoD-supported trauma trials."

25. On April 24, 2003, defendants issued a press release further promoting Hemopure and providing an update on the FDA approval process (the "April 24th Press Release").

> Biopure is seeking FDA approval to market Hemopure for the treatment of acutely anemic adult patients undergoing orthopedic surgery, and for the purpose of eliminating or reducing the need for red blood cell transfusions in these patients. As part of the BLA review process, the FDA has completed its inspections of Biopure's manufacturing and data-handling facilities and has audited its contract research partners and several clinical sites in the United States and South Africa. Biopure has responded to all questions raised by the FDA during the inspections and has resolved all previous manufacturing documentation issues with the FDA. Hemopure continues to be manufactured and is available for shipment.

26. On May 22, 2003, defendants issued a press release announcing Biopure's financial results for the Second Quarter of 2003 (the "May 22nd Press Release"). For the second fiscal quarter ended April 30, 2003, the Company reported a net loss of $11.7 million, or $0.35 per common share, compared with a net loss of $12.7 million, or $0.49 per common share, for the corresponding period in 2002. The Defendants also discussed the pending FDA application, noting:

> Based on FDA performance goals and guidelines in the Prescription Drug User Fee Act (PDUFA), Biopure is hopeful that in mid 2003 the FDA will complete its review and act on Biopure's biologic license application (BLA) to market Hemopure in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery. As part of this review, the agency has inspected the company's manufacturing and data-handling facilities and has audited its contract research partners and several clinical sites in the United States and South Africa. Biopure has responded to all questions raised by the FDA to date.

27. On May 30, 2003, defendants issued a press release entitled, "U.S. FDA Finalizes

Response Date for Biopure's Marketing Application of Hemopure (the "May 30th Press Release"). Specifically, defendants stated:

> The U.S. Food and Drug Administration (FDA) today notified Biopure Corporation (Nasdaq: BPUR) that it will complete its review and act on the company's biologic license application (BLA) for Hemopure(R) (hemoglobin glutamer - 250 bovine) by August 29, 2003. Biopure has applied to market Hemopure in the United States for the treatment of acutely anemic patients undergoing orthopedic surgery and for the elimination or reduction of red blood cell (RBC) transfusions.
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> Biopure submitted its BLA on July 31, 2002. Under FDA performance goals in the Prescription Drug User Fee Act (PDUFA III), the agency has up to 10 months from the submission date to review and act on the BLA, making the original action due date June 1, 2003. As part of the normal review process, Biopure has responded to FDA questions regarding the application. The agency has classified the latest responses submitted in mid-May 2003 as additional analyses of previously submitted data, which under FDA standard operating procedures automatically provides the agency up to three months beyond the original action due date to review the data. This type of action is not unusual- the last 11 standard BLAs accepted for review by the FDA have undergone a 13-month review.

In commenting on the FDA approval process, defendant Moore stated: "We're very pleased with the FDA's progress in reviewing our application. We continue to work closely with the agency toward a final decision that will allow us to make Hemopure available as an alternative to red blood cell transfusion. We're also continuing our preparations to roll out the product to leading orthopedic surgery centers following approval."

28. On August 1, 2003, defendants issued a press release announcing that the FDA had "completed its review of the company's biologic license application (BLA) for Hemopure." According to the August 1 Press Release:

> The [FDA] letter focuses primarily on clarification of clinical and preclinical data and includes some comments on labeling. It does not request additional clinical trials. Biopure has applied to market Hemopure in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery and for the elimination or reduction of red blood cell transfusions in these patients.

> With 30 days remaining in the original BLA review cycle, the issuance of the letter has suspended the FDA review clock until Biopure submits a complete response.

In commenting on the FDA letter, defendant Moore stated: "We're encouraged that the FDA has finished its review and provided comprehensive feedback in advance of the formal action due date. By maintaining thirty days on the review clock, the FDA is encouraging us to work with them to complete the approval process as quickly as possible. We'll work with the Agency to address the remaining questions and will provide our answers as expeditiously as possible."

29. Defendants' bullish spin on the FDA's letter had an immediate effect on Biopure's stock price. On August 1, 2003, Biopure's stock price jumped 22% to $7.30 on heavy volume.

30. On August 21, 2003, defendants issued Biopure's 2003 Third Quarter Financial Results, reporting a net loss of $11.3 million, or $0.28 per common shares, compared with a net loss of $12.6 million, or $0.43 per common shares, for the corresponding period in 2002 (the August 21st Press Release"). The press release also re-iterated the status of Biopure's FDA application, as previously announced in the August 1st Press Release.

31. Contrary to the Company's August 1st optimism, on October 30, 2003, defendants issued a press release announcing that Howard Richman, Biopure's Senior Vice President of Regulatory and Operations, was leaving Biopure "to pursue other interests" and that Biopure would not respond to the FDA latest requests for additional information until June 30, 2004, drastically delaying the approval process for Hemopure (the "October 20th Press Release"). Specifically, defendants announced:

> Biopure Corporation (Nasdaq: BPUR) today announced its plan to respond by June 30, 2004, to the Food and Drug Administration's (FDA) questions regarding its biologic

license application (BLA) for Hemopure(R) [hemoglobin glutamer - 250 (bovine)]. The company has adjusted its operating plan to reduce expenses and conserve cash while it completes its written response to the FDA.

* * *

During the past two months the company has had several substantive interactions with the FDA to clarify the Agency's questions. Many of Biopure's responses have been completed. However, some require the retrieval of source medical documents and/or historical blood transfusion data from clinical trial sites in various countries, which will take several months to complete.

* * *

Biopure has also implemented cost reductions designed to minimize its ongoing cash burn, which include reducing the workforce by approximately 30 percent and decreasing forecast manufacturing expenses for fiscal 2004.

In commenting on the delay, defendant Moore remained positive about Hemopure and FDA approval, stating: "In the best interests of our shareholders, today we've taken the steps necessary to more efficiently run our business while we complete our comprehensive response to all of the FDA's questions. We view the Agency's questions as a 'roadmap' to approval and have set a conservative, achievable target date for our response. We remain enthusiastically committed to commercializing Hemopure in the United States as expeditiously as possible."

32. On December 11, 2003, defendants issued Biopure's 2003 Fourth Quarter and Year-End Financial Results, reporting a net loss of $47.1 million, or $1.27 per common shares for the year. The press release also re-iterated the status of Biopure's FDA application, as previously announced in the October 30th Press Release.

33. The above-listed statements were false and misleading when made for the following reasons:

a. Defendants failed to disclose all material facts and information about Biopure's Hemopure applications with the FDA, including all material,

adverse communications received from the FDA concerning Hemopure's safety;

b. Defendants failed to disclose that in March 2003 Biopure submitted a trauma protocol for Phase II clinical trial of Hemopure for the treatment of "hemorrhagic shock casualties in the hospital setting" and that the FDA placed this trauma protocol under a new investigational drug application;

c. Defendants failed to disclose that by May 2000, the FDA placed a "clinical hold" on Biopure's proposed trauma trial "due to safety concerns";

d. Defendants failed to disclose that in June/July 2003, the FDA requested that the Company perform three additional pre-clinical animal studies of Hemopure in conscious swine to address safety and dosage concerns before any trials would be allowed on humans and that despite Biopure's submission of additional finding, the FDA still refused to allow the Hemopure trauma study;

e. Defendants failed to disclose that based on adverse event data submitted with the Company's Phase III orthopedic surgery trial, the FDA had voiced "safety concerns" about Hemopure that would prevent clinical studies for trauma and, at best, severely delay approval for use in orthopedic surgery; and

f. Defendants mischaracterized the FDA's July 31, 2003 letter as a sign that Hemopure was close to approval when, at best, it would take the Company

until mid-2004 to address the FDA's safety concerns.

THE TRUTH IS REVEALED

34. After the close of trading on December 24, 2003, at 5:52 p.m., defendants issues a stunning press release announcing: (1) that the Company, defendant Moore and a former vice president had each received Wells notices from the SEC related to the Company's inadequate disclosures concerning communications with the FDA about the Hemopure's applications; and (2) that in March 2003 – undisclosed to the public – the Company had filed an application with the FDA for the use of Hemopure in clinical trauma studies, but that the FDA had repeatedly blocked the trial due to material safety concerns. Specifically, the Company announced:

> Biopure Corporation (Nasdaq: BPUR) reported that on December 22, 2003, it received a "Wells Notice" from the staff of the Securities and Exchange Commission (SEC) indicating the staff's preliminary decision to recommend that the SEC bring a civil injunctive proceeding against the company. As permitted under the Wells process, Biopure intends to respond promptly and thoroughly in writing before the SEC staff formally decides what action, if any, to recommend. The company's chief executive officer and its former senior vice president of Regulatory and Operations also received Wells Notices.
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> Biopure believes the notices relate to the company's disclosures concerning its communications with the Food and Drug Administration (FDA) about a trauma study protocol the company submitted to the Agency in March 2003 and about the company's biologics license application (BLA) for Hemopure(R) [hemoglobin glutamer - 250 (bovine)]. The company did not publicly disclose its communications with the FDA about the proposed trauma protocol and investigational new drug application (IND) because it does not believe communications about proposed clinical trials are material prior to the initiation of a trial.

Several months after the fact, the Company provided its first details about the failed trauma study applications and the defendants' communications with the FDA.

> [In March 2003] Biopure submitted the trauma protocol for a Phase II clinical trial of Hemopure for the treatment of hemorrhagic shock casualties in the hospital setting, where

red blood cell transfusions are available. The FDA placed this trauma protocol under a new IND that is separate from the company's previous IND and its BLA to market Hemopure for the treatment of acutely anemic adult patients undergoing orthopedic surgery and for the elimination or reduction of red blood cell transfusions in these patients. The protocol sought to administer up to 15 units of Hemopure, a proposed dosage that was 50 percent higher than administered in previous clinical trials.

After the in-hospital trauma protocol was submitted to the FDA and the new IND was assigned, the Agency placed a clinical hold on the proposed trauma trial due to safety concerns. The FDA referred to a review of adverse event data from the company's Phase III orthopedic surgery trial, which was submitted in the BLA. The data from that Phase III trial has been previously presented at medical meetings.

In May 2003, Biopure responded to the FDA's clinical hold and also filed the response as a BLA amendment because it discussed data previously submitted with the BLA. That amendment resulted in the FDA extending its BLA review period up to 90 days, as previously announced on May 30, 2003. The Agency also requested three additional pre-clinical animal studies of Hemopure in conscious swine to address its concerns regarding high-volume administration. After the company's responses, the FDA has twice declined to lift the clinical hold, most recently in a letter dated July 30, 2003. This letter is separate from the FDA complete response letter Biopure received on that date in response in to its BLA for orthopedic surgery. The questions in the FDA's trauma letter were the same as some of the questions in the BLA complete response letter and had two additional questions, one about the company's analysis of age-specific effects in individuals over age 75 in the Phase III orthopedic surgery trial and a second question about dosing.

35. The market's reaction to Biopure's announcement was swift and severe. On December 26, 2003, the next trading day, the Company's shares closed down 39 cents, or 14%, to close at $2.43, far from the Class Period high of $8.25 per share.

36. Moreover, the timing of the Company's Christmas Eve announcement was met with extreme skepticism. On December 25, 2003, the Boston Globe reported on the "unusual Christmas Eve news release", quoting a former chairman of the American Bar Association's Committee on Federal Regulation of Securities, who commented: "From a public perception and market credibility point of view, it doesn't help that it appears the company is trying to slip information in on a slow day."